Remarks/Arguments:

Applicants wish to thank Examiner Ja-Na Hines for the courteous consideration rendered applicant Thomas Hartung, Ph.D., and applicants' undersigned representative during an interview at the PTO on 5 February, 2008. A statement of the substance of the interview was filed March 12, 2008, in the PTO.

Claims 23-34, newly presented hereby, are pending.

Claims 1-22 are cancelled, without prejudice or disclaimer.

Present, method claims 23-34 replace method claims 19-22, which were rejected in the final Office Action. Support for the new claims can be found in original claims 1-18 and throughout the present specification, as further explained below.

Present claim 23 is independent. Present claims 24-34 are dependent, directly or indirectly, on present claim 23.

Present claim 23 provides:

> A method of testing blood for reaction to a substance comprising the steps of:
> - selecting a cryopreserved unit dose of a blood product and a cryopreservative from among a plurality of identical cryopreserved unit doses obtained from a single or pooled sample of blood taken from a human or animal;
> - thawing the cryopreserved unit dose;
> - contacting the thawed, cryopreserved unit dose with the substance; and
> - determining, by biological, physical, chemical, or physicochemical means, whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction.

Accordingly, the presently claimed method is for "testing blood" to determine whether "an immunofunctional, toxic or modulatory blood reaction" occurs upon contacting the blood with a

particular "substance." In other words, the presently claimed method (in accordance with claim 23) tests a substance to determine whether it would cause "an immunofunctional, toxic, or modulatory blood reaction" in an individual (human or animal).

More precisely, the presently claimed method tests a substance to determine whether it causes "an immunofunctional, toxic, or modulatory blood reaction" with blood cells of a given individual, (a) by selecting "from among a plurality of identical cryopreserved unit doses" a single "cryopreserved unit dose" (with each of the identical cryopreserved unit doses being "a blood product" combined with "a cryopreservative"). In other words, as starting material, the presently claimed method requires "a plurality of identical cryopreserved unit doses," i.e., one or more samples of blood (i.e., "a single or pooled sample of blood") taken from a single human or animal is combined with a cryopreservative and divided into the "plurality of identical cryopreserved unit doses" (alternatively, the cryopreservative can be added after the sample is divided into identically sized unit doses). This starting material, in and of itself, provides a significant advantage over prior art blood tests in that, from one blood sample (single or pooled) from a given individual, multiple identical unit doses are obtained, cryopreserved, and stored for later multiple test procedures, i.e., more than one test procedure can be performed starting from as little as a single blood sample from a human or animal. As described in the present specification (page 10, lines 4-10):

> The volume of whole blood that can be drawn at one time from a healthy human donor allows preparation of several thousand unit doses of, for example, 100 microliters. The unit doses can be combined in sets of, for instance, 5, 10 or more unit doses . . . They can be introduced into commerce while the deep chilling is maintained. The set can, for specific applications, contain not only units with unit doses, but also units with a multiple of the unit dose.

> The particular unit dose can otherwise contain the same components and have the same composition, and be prepared and used in the same manner, as preparations containing the previously presented described deep-frozen blood.
>
> Present claims 24 and 25 provide:
>
> 24. The method of claim 23 wherein the blood product comprises leukocytes.
>
> 25. The method of claim 23 wherein the blood product comprises whole blood.

As such, claims 24 and 25 are sub-generic with respect to the (generic) "blood product" limitation of present claim 23. In an embodiment according to present claim 24, the "blood product" (used in the presently claimed method) can be constituted by white blood cells (i.e. "leukocytes"), alone; whereas in an embodiment according to present claim 25, the "blood product" contains at least "whole blood" (present specification, page 5, line 10).

Present claims 26-28 limit present claims 23-25, respectively, to a "blood product" that "further comprises clotting inhibitors." Present claims 29-34 limit claims 23-28, receptively, to a "blood product" that "further comprises diluents" (original claim 8).

Claims 19-22 were objected to for beginning with the phrase "In a method." Since none of the present claims recites the phrase at issue, the objection is rendered moot. Withdrawal of the objection appears to be in order.

Claims 19-22 were rejected under 35 USC 112, second paragraph, for allegedly being indefinite. Reconsideration is requested.

The rejected claims are allegedly indefinite for reciting the word "standardized"—in the recited phrase "standardized blood unit dose." Since none of the present claims recites the word "standardized," the rejection is rendered moot. Withdrawal of the rejection appears to be in order.

Claims 19-22 were rejected under 35 USC 102(b) as allegedly anticipated by each of *Proc. Natl. Acad. Sci. USA, 92*, 1995, 10119-10122 (Rubinstein) and *J. Virol. Methods, 35*, 1991, 217-226 (Kaye). Reconsideration of the rejections is requested.

For anticipation under §102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "identically appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

Rubinstein discloses the processing and cryopreservation of placental/umbilical cord blood for unrelated bone marrow reconstitution. The object of Rubinstein ("Discussion" on page 10121, last paragraph) is to provide smaller blood units and, so, provide advantages of convenience, cost, and efficiency—particularly with respect to the reduction of storage space. According to the teachings of Rubinstein (page 10119, abstract, lines 8-11, and page 10120, left hand side column),

eliminating red-blood-cell bulk and plasma effects a "leukocyte-rich supernatant," which is centrifuged to produce a leukocyte concentrate.

Kaye (page 218) describes a method for the storage and preservation of whole blood samples in a glycerol/gelatin-based medium. DNA—suitable for replicating by polymerase chain reaction (PCR)—can be extracted from these samples after storage for up to 3 months. Suitability was evaluated by testing DNA extracted from the stored samples of blood taken from asymptomatic homosexual men.

The presently claimed invention provides—for the first time—(1) a ready-to-use (after thawing) unit dose of frozen blood cells as a reagent (i.e., tool) in a method for testing (i.e., predicting) whether a particular material would elicit an immunofunctional toxic, or modulatory blood reaction in a human or non-human animal and (2) multiple, identical, cryopreserved, blood-cell containing (e.g., leukocytes and whole blood) unit doses obtained from a single human or non-human animal, from which the ready-to-use unit dose is selected. Significantly, each of the unit doses is ready to use, in that it contains a cryopreservative, which need not be removed before use.

The presently claimed method clearly distinguishes over each of Rubinstein and Kaye in that the present claims use a blood-cell containing "blood product" as a reagent/tool for testing with other substances, rather than testing within a cell-containing unit dose, itself, such as described in each of Rubinstein and Kaye. More precisely, the presently claimed method is limited to contacting the thawed, cryopreserved unit dose with the substance; and determining . . . whether the unit dose reacts

with the substance" (emphasis added), which limitations are absent from each of Rubinstein and Kaye.

The "absence" from each of Rubinstein and Kaye of the limitations (emphasis added)

- contacting the thawed, cryopreserved unit dose with the substance; and
- determining, by biological, physical, chemical, or physicochemical means, whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction

on the present claims "negates anticipation" of any of the present claims by either one of the references. *Kolster Speedsteel AB*, 230 USPQ at 84. Since each limitation on the present claims does not "identically appear" in either Rubinstein or Kaye, neither reference can anticipate any of the present claims. *Gechter*, 43 USPQ2d at 1032. Withdrawal of both the §102(b) rejection based on Rubinstein and the §102(b) rejection based on and Kaye appears to be in order.

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By _____
William E. Player
Reg. No. 31,409

400 Seventh Street, NW
The Jenifer Building
Washington, D.C. 20004
Tel. (202) 638-6666
Fax (202) 393-5350
Date: June 3, 2008
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